

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth Stewart Confirmation No. 6917  
Serial No.: 10/634,368 Art Unit: 3735  
Filed: August 6, 2003 Examiner: Shaffer, Richard R.  
For: Bone Instrumentation Cover Or Shield

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents  
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Alexandria, VA 22313-1450

Barnes & Thornburg Customer No: <b>23646</b> U.S. Patent and Trademark Office
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Sir:

I, Jeffery Thramann believe and declare as follows:

I am a founder and currently serve as Chairman of the board of Lanx, Inc. Lanx, Inc. manufactures and supplies spinal instrumentation to purchasers in the United States and abroad. I received a medical degree from Cornell University and completed general surgical training as well as neurosurgical training and a spine fellowship at the Barrow Neurological Institute. I have performed thousands of surgeries on and about the human spine including the placement of implanted spinal instrumentation. Such spinal instrumentation includes screws, hooks, rods, plates, and interbody cages and grafts. I also am acquainted with surgical treatment throughout the human body from my studies and associations with other surgeons.

I am aware of the statement in the 02 October 2009 office action in the above-identified application that "the device [of Ellman] is fully capable of being sized and shaped for separating bone instrumentation from the surrounding body tissues. In the same way that Ellman protects an organ from the surrounding tissues, it could also protect the body from any projecting portion of bone instrumentation." However, it is my opinion that Ellman teaches exactly the opposite of the statement in the office action.

Ellman discloses a “surgical net bag for encapsulating a fractured organ during surgical repair.” [Abstract] Ellman further discloses that the bag may be woven mesh comprising strands separated by large openings or made of a sheet material having “holes 3-9mm in size with a center-to-center spacing of about 4-10mm”. [2:30-60] Ellman further discloses that after tightening the bag around an organ, “the surgeon can proceed to suture across the wound. The sutures 26 are extended through the mesh opening 19 adjacent the wound so that they wrap around the mesh threads 16, and are thus prevented from pulling out of the friable spleen tissue.” [3:10-20] Ellman further discloses that “another advantage is that the multiple interstices or **openings in the net allows ingrowth of tissue through the net openings** and around the net solid parts and thus enhances healing.” [3:55-58; emphasis added] Having reviewed both Ellman and the above cited application, I conclude that Ellman’s device would not “provide a medically safe physical barrier between the part of the bone instrumentation and the surrounding bone and soft tissue...” nor would it “prevent ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation” as recited in claim 23, is not “adapted to separate the part of the pedicle screw from surrounding bone and soft tissue...” nor would it “prevent ingrowth of bone or tissue through the cap” as recited in claim 30 and is not a “means... for providing a medically safe physical barrier between the part of the bone instrumentation and the surrounding bone and soft tissue” nor would it “prevent ingrowth of substantially all of the surrounding soft tissue” as recited in claim 36. Ellman specifically teaches a bag adapted to cause contact through the bag with the surrounding tissue and encourage tissue ingrowth through the bag whereas applicant specifically claims a cover adapted to provide a barrier and prevent ingrowth.


I am aware of the statement in the 02 October 2009 office action in the above-identified application that Coombs “is fully capable of creating and providing a medically safe barrier to protect soft tissue, which may prevent ingrowth.” However, it is my opinion that Coombs is not capable of ingrowth prevention as urged in the above-quoted statement in the office action.

Coombs is directed to an orthopaedic external fixation device for connecting bone pins to the fragments of a fractured bone to form a support holding the bone fragments in a desired positional relationship while the fracture re-unites. Coombs device is for “external” fixation (see column 1, line 4 and line 48) and in the portion of Coombs describing how the device is used (see especially column 4, lines 6-28) it is evident Coombs’ device is not adapted for placement

within a patient's body to fit between the implant and soft tissue so as to prevent ingrowth. Furthermore, Coombs does not disclose that his device is made of medically safe material such that it could be used to prevent ingrowth of soft tissue with respect to the implant.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

  
Jeffery Thramann

  
Date